K003925

JAN - 8 2001

0-000058

Attachment 4

Summary of Safety and Effectiveness

Submitter's Name/Contact Person

The submitter of this special 510(k) is:

Cordis Neurovascular, Inc.
14000 N.W. 57th Court
Miami Lakes, Florida 33014

Establishment Registration No. 1058196

Contact: Amarilys Machado
Regulatory Affairs Associate II

Tel: (305) 512-6493
Fax: (305) 512-6520

December 18, 2000

Trade Name / Common Name

Trade Name: Prowler® Infusion Catheters with pre-shaped tips

Common/Classification Name: Infusion Catheters

Classification

Class II

Performance Standards

The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards.

Intended Use and Device Description

The Prowler® Infusion Catheters with pre-shaped tips are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems (Neuro, Peripheral, Coronary), for Guidewire Exchange/Support, and for superselective angiography of the peripheral and coronary vasculatures.

Device Description

The Prowler® Infusion Catheters with pre-shaped tips are a single lumen catheter featuring a stiff proximal shaft and a flexible distal section. The catheter's inner diameter accommodates guidewires of .018" and smaller depending on the catheter type. The catheter body is radiopaque with a distinguishable marker(s) at the distal tip. It includes a hydrophilic coating on the outside of the shaft as well as a PTFE liner on the inner lumen.

Continued on next page

Summary of Safety and Effectiveness, Continued

0-000059

Predicate Devices

The predicate devices are listed in the table below:

Devices	Company	Product Code	510(k) Number
Prowler® Infusion Catheters	Cordis Neurovascular, Inc.	79KRA	K965181 K972518
Prowler® Plus Infusion Catheters	Cordis Neurovascular, Inc.	79KRA	K99326

Summary of Studies

Design verification testing showed that the Prowler®Infusion Catheters with pre-shaped tips perform as well or better than the predicate devices tested. No new questions of safety and effectiveness were raised. Design verification testing included:

Catheter Tip Shape

- Quantitative Simulated Use Shape Retention
- Post Shaping Inspection (Shape Verification, Dual Marker Band Inspection)
- Post Sterile Shape Verification
- Post Sterile Static Burst Pressure Test
- Post Sterile Pull Strength Test

Packaging

- Visual Packaging
- Environmental Exposure Testing

All materials used in the Prowler® Infusion Catheters with pre-shaped tips are biocompatible.

Summary of Substantial Equivalence

The Prowler® Infusion Catheters with pre-shaped tips are substantially equivalent to the previously cleared Prowler® Infusion Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2001

Ms. Amarilys Machado
Cordis Neurovascular, Inc.
P.O. Box 025700
Miami, FL 33102-5700

Re: K003925
Prowler® Infusion Catheters with pre-shaped tips
Regulatory Class: II (two)
Product Code: 74 KRA
Dated: December 18, 2000
Received: December 20, 2000

Dear Ms. Machado:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): The 510(k) number has not yet been assigned. : K003925

Device Name: Prowler® Infusion Catheters with pre-shaped tips.

Indications for Use Statement

The Prowler® Infusion Catheters ~~with pre-shaped~~ tip are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems (Neuro, Peripheral, Coronary), for Guidewire Exchange/Support, and for superselective angiography of the peripheral and coronary vasculatures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 1/

OR

Over-The-Counter Use_____

Division of Cardiovascular & Respiratory Devices
510(k) Number K003925